

SUMMARY OF ALLEGATIONS

1. GSK routinely paid kickbacks to physicians to influence physicians' choice of prescription drugs and in exchange for the referral of patients to certain products. GSK financially rewards those physicians who prescribe their products the most. GSK also provides financial incentives to those physicians who potentially could prescribe significant quantities of their products. GSK's illegal inducements come in many forms, including, but not limited to, cash payments, theater and sporting event tickets, dinners, and all-expense paid resort vacations.

2. Driven by a desire to generate large profits, GSK induced physicians to prescribe drugs manufactured by its company. The greater amount of GSK's drugs that a physician prescribes, the greater the reward that they will receive from GSK for doing so. These arrangements skew the selection of drugs prescribed to beneficiaries of Government-funded health benefit programs and the physicians' selection of patient drug therapies.

3. GSK's schemes result in the payment of illegal kickbacks to physicians in exchange for referral of patients to the manufacturers' products. In effect, GSK caused physicians to steer patients to specific drug products in return for compensation based on the volume and dollar value of the medication referrals made.

4. GSK has systematically defrauded Government-funded health benefit programs by engaging in fraudulent conduct to induce excessive referrals and unnecessary reimbursements or cause excessive and unnecessary reimbursements to be claimed.

5. To increase its prescription drug market share and its profits, GSK routinely pays kickbacks and illegal remuneration to physicians and hospitals to induce physicians to prescribe Paxil, instead of competing drugs. The kickbacks GSK pays to prescribing physicians and hospitals take many forms including, but not limited to, all expense paid trips intended to increase prescribing, “consulting” honoraria, grants, free textbooks, drug price discounts and other inducements. By paying illegal kickbacks in violation of 41 U.S.C. § 51, *et seq.* (the “Anti-Kickback Act of 1986”) and/or 42 U.S.C. § 1320a-7b(b) (the “Medicare/Medicaid Anti-Kickback Statute”) and offering price discounts to physicians and institutions that are not disclosed to the Government, GSK has caused and/or induced physicians and hospitals who sought reimbursement for GSK drugs from federal Government-funded health insurance programs to file false claims in violation of the FCA.

6. GSK’s tactics frequently moved market share to specific drugs, causing over utilization of GSK prescription medications. As a result, GSK facilitated and caused the false, fraudulent and improper billings, inducing Medicare, Medicaid and other federally-funded programs to pay excessive reimbursements at taxpayer expense.

7. In summary, GSK engaged in various false and fraudulent practices designed to enhance its market share and profits at the expense of the United States Treasury and in disregard of patient welfare.

INTRODUCTION

8. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false statements and false or fraudulent claims made or caused to be made by GSK to the United States in violation of the False Claims

Act, 31 U.S.C. §§ 3729, *et seq.* (the "FCA"). The false or fraudulent claims and statements at issue involve payments made by Government-funded health insurance programs, such as the Federal Employees Health Benefits Program ("FEHBP"), TRICARE/CHAMPUS, Medicare and Medicaid for prescription drugs.

9. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

10. The FCA provides that any person who knowingly submits or causes to submit to the Government a false or fraudulent claim for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government. The Act empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal without service on any Defendants. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

11. Pursuant to the FCA, Relator seeks to recover, on behalf of the United States, damages and civil penalties arising from false or fraudulent claims that GSK submitted or caused to be submitted to Government-funded health insurance programs.

PARTIES

12. Relator Joseph Piacentile is a physician and a resident of New Jersey. Dr. Piacentile brings this action for violations of the FCA on behalf of himself and the United

States pursuant to 31 U.S.C. § 3730(b)(1). He has knowledge of the violations and allegations discussed herein.

13. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (“GSK”) is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania, and is a subsidiary of GlaxoSmithKline plc, an English corporation with operational headquarters in Research Triangle Park, North Carolina and Philadelphia, Pennsylvania. GSK is one of the world’s largest research-based pharmaceutical companies, and is an integrated, research-based group of companies whose primary corporate purpose is to discover, develop, manufacture and market throughout the world various medicines. GSK is known as a leader in respiratory, anti-viral (including AIDS/HIV), and central nervous system research. Other therapeutic research areas include: cardiovascular, oncology, critical care, and metabolic diseases such as diabetes. The company’s worldwide sales exceeded \$35 billion in 2003. GlaxoSmithKline plc was formed in January 2001 as a result of the merger between Glaxo Wellcome plc (“Glaxo”) and SmithKline Beecham plc (“SmithKline”).

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730.

15. The Court has personal jurisdiction over GSK pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and GSK has sufficient minimum contacts with the United States.

16. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because GSK can be found, resides or transacts, or has transacted business in the Eastern District of Pennsylvania and/or at least one act proscribed by 31 U.S.C. § 3729 occurred in the Eastern District of Pennsylvania.

17. Pursuant to 31 U.S.C. § 3730(b)(2), the Relator must provide the Government with a copy of the Complaint and/or a written disclosure of substantially all material evidence and material information in its possession contemporaneous with the filing of the Complaint. Relator has complied with this provision by serving copies of the original Complaint and this Fifth Amended Complaint on Kathleen Meriwether, Esq., Assistant United States Attorney for the Eastern District of Pennsylvania, and the Honorable Alberto Gonzalez, the Attorney General of the United States of America. Relator is unaware of any “public disclosure” in connection with the false claims alleged in this Complaint as defined in 31 U.S.C. § 3730(e)(4)(A).

ALLEGATIONS

Government-funded Health Insurance Programs

18. Medicare is a federally-funded health insurance program primarily benefiting the elderly that was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare is administered by the federal Health Care Financing Administration (“HCFA”). While Medicare does not pay for over-the-counter drugs or most self-administered prescription drugs, it does pay for certain categories of drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare covers certain drugs used in association with dialysis or organ transplantation, chemotherapy and

pain management in cancer treatments. The program also reimburses the cost of certain types of vaccines such as those for influenza and hepatitis B.

19. Medicaid was created at the same time as Medicare in 1965 when Title XIX was added to the Social Security Act. Medicaid is a public assistance program to provide payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal Government and those state governments that choose to participate in the program. For instance, in Pennsylvania during fiscal year 2004, the federal Government paid 57.6% of the cost of State expenditures for assistance payments, medical services and medical insurance services under the Medicaid program. The federal Government also separately matches certain state expenses incurred administering the Medicaid program. While specific Medicaid coverage guidelines vary from state to state, Medicaid's coverage is generally modeled after Medicare's coverage, although Medicaid usually provides more expansive coverage than does Medicare.

20. Medicaid coverage for prescription drugs is significantly more expansive than that provided by Medicare. Although payment for prescription drugs is an optional service that States may choose to include in or exclude from the Medicaid programs, virtually every State has included basic prescription drug coverage in its Medicaid plan.

21. TRICARE is the military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The system operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit

program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits. Five managed care support contractors create networks of civilian health care providers. Military prescription drug benefits are provided through three programs: military treatment facility; outpatient pharmacies, TRICARE contractor retail pharmacies; and a national contractor's mail-order service. In 2005, the military spent approximately \$6.0 billion on pharmacy benefits.

22. FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management and collectively pay more than \$2 billion annually in prescription drug benefits.

23. The Anti-kickback Statute, 42 U.S.C. § 1320a-7b (b), provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to \$25,000 and imprisonment for up to 5 years.

24. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-kickback Statute. In addition, the Balanced Budget Act of 1997 amended section 1128A(a) of the Act to include an administrative civil money penalty provision for violating the anti-

kickback statute. The administrative sanction is \$50,000 for each act and an assessment of not more than 3 times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. §1320a-7a(a)(7).

25. In accordance with the Anti-kickback Statute, Medicare and Medicaid regulations directly prohibit any provider from paying or receiving remuneration with the intent to induce referrals that take into account the volume or value of any referrals or business generated. *See, e.g.*, 42 C.F.R. § 1001.952(f). Such remuneration amounts to a kickback and can increase the expenditures paid by Government-funded health benefit programs by leading to over utilization of prescription drugs, inducing medically unnecessary and excessive reimbursements. Kickbacks also have the effect of reducing a patient's healthcare choices as unscrupulous or unknowing physicians steer their patients to various drug products based on the physician's own financial interests rather than the patient's medical needs.

26. The Anti-kickback Statute contains five statutory exceptions from the statutory prohibitions and other regulatory "safe harbors" have been enacted to exclude certain types of conduct from the reach of the Anti-kickback Statute. None of the statutory exceptions or regulatory safe harbors protect GSK's conduct as set forth in this Complaint.

**GSK Engaged in Aggressive Marketing of
Their Kickback Schemes To "Buy" Physician Loyalty**

27. Relator Piacentile conducted a significant amount of independent investigation prior to filing this action. He met with numerous people, including consultants hired by GSK to arrange kickbacks to the physicians, certain of GSK's drug

representatives and numerous physicians who received kickbacks from drug companies. Dr. Piacentile also attended events offered by GSK.

28. Through its sales representatives and marketing organizations, GSK provides kickbacks to physicians in a wide variety of ways, ranging from very expensive trips and cash payments to less expensive meals and entertainment. The range of activities is designed to appeal to different interests and pursuits in the hope of finding each physician's "hot button."

29. GSK planned conferences at attractive locations and provided physicians with all-expense paid transportation and accommodations, often with a guest, spouse and/or children included.

30. Dr. Piacentile attended one conference presented by GSK to promote its drug Paxil, an antidepressant. The conference is representative of the great lengths to which GSK goes to influence the physicians who prescribe their products.

31. GSK held its "consultant's input meeting" program at the Wyndham El Conquistador resort in Puerto Rico on April 27 - 30, 2000 to promote Paxil to a crowd of approximately 170 physicians. The conference was formally called "Forum 2000: Perspectives on Psychiatry for the Future — A Consultants' Input Meeting." The Wyndham is described as one of only two Caribbean five-diamond resorts. Physicians and a guest or their families were flown to Puerto Rico and provided with luxury accommodations, meals and recreation in exchange for attending a few lectures promoting GSK products. Including guests and family members, about 500 people attended the meeting.

32. Dr. Piacentile attended the Puerto Rico conference as the guest of an

invited physician, where the doctors were treated to every luxury. They were given leather portfolios as gifts. They were provided airport transfers, rooms costing more than of \$250 per day, and valet parking. GSK even arranged to prepay all gratuities. The doctors and their families had access to exclusive country clubs, luxury spas, and world-class golf courses in Puerto Rico. Physicians and their guests were also offered the opportunity to sail, snorkel, hike in the El Yunque Rainforest, go horseback riding, and kayaking. They were treated to cocktail receptions, dinners and shows. A children's program was provided on Saturday night. The physicians were also paid \$750 for their participation and an additional \$100 to cover "incidental meeting related expenses," such as telephone, honor bar or other hotel services.

33. In an unsuccessful attempt to fall within the AMA's ethical guidelines and avoid having its Puerto Rican junket being labeled a kickback, GSK entered into a "consulting agreement" with each physician participant. The consulting agreement described the purpose of the Puerto Rico meeting:

The purpose of the meeting will be to provide GSK with your scientific/medical opinions on scientific, clinical and marketing issues that will assist in bridging the gap between clinical trials and clinical practice in the management of mood and anxiety disorders. In addition, attendees will learn about and help determine how to most effectively deliver educational messages.

The agreement also defined the physician's obligations under "Scope of Work:"

- a. You will attend and participate in all academic sessions and workshops.
- b. You will provide scientific and clinical opinions based on your experience with paroxetine and other selective serotonin reuptake inhibitors.

34. Both the defined purpose of the Puerto Rico meeting and the “scope of work” were fabricated pretexts to help convince physicians that the money, airfare and accommodations provided by GSK were not kickbacks paid in exchange for prescribing Paxil. In fact, academic sessions and workshops were only scheduled during the afternoon on April 28, 2000 from 1 p.m. to approximately 4 p.m. and from 8 a.m. to noon on Sunday, April 29. Only one session was set aside to obtain “consultant input.” Many of the remaining workshops discussed various topics unrelated to the stated purpose of the meeting, such as “The Internet, Psychiatry, and the Future.”

35. One of the workshops presented during the Puerto Rico meeting instructed the doctors how they could “earn” another \$1,000 for 20 minutes of their time. GSK participates in the Initiative for Social Anxiety Assessment and Care (“ISAAC”), which is a nationwide physician and patient registry designed, among other things, to raise awareness of social anxiety disorder and provide physicians with easy access to screening instruments and diagnostic tools. Patients who enroll in ISAAC complete a “self-assessment survey.” According to GSK, physicians incur a “minimal time investment (2-3 min/patient)” to enroll a patient but are paid a \$100 administrative fee for each patient enrollment up to ten patients. Regardless of the intended benefits of the ISAAC program, if any, GSK has structured physician participation in such a way that the \$1,000 payment is nothing more than a kickback.

36. GSK also promoted Paxil at an “Advisory Panel” meeting held at the Short Hills, New Jersey Hilton Hotel on March 3, 2000. The meeting included dinner and a \$200 cash honorarium for each of the 12 doctors who attended.

37. Upon information and belief, GSK held a Paxil-related “Faculty

Development” conference at the Fairmont Miramar Hotel in Santa Barbara, California from January 24 to January 26, 2003. The doctors each received a \$750.00 honorarium for participating, and received free transportation (other than airfare), lodging and meals.

38. GSK also frequently schedules “Dash ‘n Dine” events for physicians. The GSK detailer arranges for physicians to stop by a restaurant on their way home. Each physician orders a take-out dinner for his family. While the meal is being prepared, the detailer spends time with the physician, promoting GSK’s products. The physician then takes dinner home to his family, often with coupons for free video rentals. The “Dash ‘n Dine” is a common kickback used by GSK.

39. According to Bill Mueller, a GSK detailer, GSK uses a ranking system to target doctors who are likely to prescribe heavily their products. The system is designed to be a rough measurement of the physician’s potential for writing prescriptions and the physician’s history in prescribing GSK products. The system tracks seven or eight specific drugs, including drugs manufactured by competitors, and identifies the exact number of prescriptions that the physician writes for those drugs during a prescribed period. GSK looks to the “power of a doctor’s pen” in deciding whom to target with kickbacks.

40. GSK promoted its antiviral drug Valtrex at a “speaker’s education” program for about 175 physicians at Charleston Place in Charleston, South Carolina from March 12 - 19, 2000.

41. GSK also held a number of events to promote Wellbutrin, an antidepressant and smoking deterrent:

a. In March 2000, GSK hosted a conference at Marina Del Ray,

California.

b. On May 8, 2000, GSK hosted a dinner at Il Capriccio in Whippany, New Jersey. After dinner, physicians and their guest were given an honorarium and two tickets to the Broadway production of their choice.

c. On June 28, 2000, GSK provided a group of physicians and their guests with tickets to the Broadway production "Fosse."

d. In June 2000, GSK took a group of physicians to dinner at the Chart House restaurant in Weehawken, New Jersey and for a boat ride. The physicians then received tickets to the Broadway production "Aida."

42. Not all drug companies take GSK's approach. Rose Mary Doscher, a drug representative for Roche Labs, told Relator Piacentile that Roche Labs does not use all-expense paid conferences to entice doctors to its products. Although Roche holds educational conferences for doctors, the conferences are low on social and recreational opportunities and high on continuing medical education. In addition, Roche does not pay for airfare or hotel accommodations, instead requiring that the doctors pay their own way. Roche also does not pay honoraria for attending meetings, although it does pay honoraria to speakers. According to Ms. Doscher, Roche believes that paying for attendees' airfare, hotel expenses and honoraria is unlawful.

**GSK Hired Consultants to Assist in Targeting
Physicians and Planning the Distribution of Kickbacks to Them**

43. GSK's efforts to reward doctors for prescribing its medications are not limited to the activities of their individual representatives. GSK established sophisticated marketing organizations and hired outside consultants to identify key physician targets and plan extravagant events.

44. GSK hired Gray Consulting, Inc. (“Gray Consulting”) to assist in organizing at least three conferences devoted to marketing Paxil during 2000. GSK spent approximately \$3 million for those conferences and provided all-expense paid transportation, accommodations, meals and recreation to approximately 600 doctors at a cost of about \$5,000 per doctor. The result of its efforts were startling: Paxil gained approximately 4% in market share within several months after the conferences occurred.

45. Scott Gray of Gray Consulting revealed to Dr. Piacentile that his company is routinely hired by pharmaceutical companies, including GSK, to identify physicians to target with lavish trips and to execute the trips. Gray indicated that the cost of each trip is typically \$3,000 to \$4,000 per physician, and that the purpose of such trips is to move market share in the company’s products. Rather than mailing doctors a check as an honorarium for participating in a meeting, Gray Consulting prefers to have the doctor “get wine and dine and walk away with a check.” Gray thinks it has more of an impact to give the doctor a check on the spot and argued that other companies are doing it, so everyone should follow the custom. The full extent of these kickbacks will be easily determined once these records are obtained in discovery. Defendants already have these records in their possession and can determine the scope of the conduct alleged.

46. By way of example during the first half of 2000, Gray Consulting was involved in 330 trips and conferences for pharmaceutical companies, including trips to the British Open in Scotland, ‘Hershey, Pennsylvania,’ the Cara Day Resort in San Diego, and many locations in California. Gray estimates that the pharmaceutical industry is spending \$18 billion annually to “wine and dine” physicians. In Gray’s view, doctors prescribe medications based on the company that gave them the best trip.

47. Dr. Piacentile also met with Carolyn Plant, General Manager, and Malcolm West, Regional Sales Director, for McGettigan Partners. Like, Gray Consulting, McGettigan Partners provides physician prescription data to pharmaceutical manufacturers and plans conferences and other events for drug company clients. McGettigan provides services for many pharmaceutical companies, including GSK.

48. McGettigan Partners predicted that 2000 was going to be a “boom year” for physician conferences because GSK rolled out a nationwide program through which all dinner meetings are planned by McGettigan and a McGettigan representative is assigned to each GSK regional office.

49. McGettigan Partners told Dr. Piacentile that the “going rate” for honoraria paid for attending a dinner meeting is \$50 to \$200. For attending a weekend “consultant meeting,” \$500 is common with an additional \$100 for expenses.

50. As part of their strategy, drug companies also target physicians to become speakers at the consultant meetings. Speakers are given cookie-cutter presentations by the drug company, complete with slides and PowerPoint presentations. They are paid \$2,500 for their speaking role.

51. Ms. Plant also told Dr. Piacentile that it is “absolutely” true that doctors do not show up for consultant conferences unless they get paid. The \$500 honorarium is essential to obtaining participation.

52. Gray Consulting and McGettigan Partners maintain records on the amount of honoraria that are paid to each doctor. This information is reported on an IRS Form 1099 that is sent to the doctor at the end of the year.

53. While Dr. Piacentile’s investigation revealed the specific examples of

wrongdoing discussed in this complaint, it also demonstrated that GSK routinely compensates physicians in, literally, thousands of different ways.

54. GSK's kickback schemes are designed primarily to increase patient referrals to GSK's products, and achieve their goal by paying kickbacks to physicians. At least one study has shown that kickbacks to doctors have increased prescribing patterns, including drugs with large marketing budgets such as Paxil.

55. The value of GSK's kickbacks is the cost of the kickback received by the physician plus the unnecessary reimbursement paid by the Government-funded health benefit program.

56. GSK knowingly engaged in the fraudulent conduct described in this complaint for the purpose of enriching itself and obtaining increased prescription referrals and reimbursements from Government-funded health benefit programs.

57. By paying kickbacks to physicians, GSK violated applicable statutes and regulations, encouraged over utilization of potentially unnecessary prescription drugs, induced excessive payments from Government-funded health benefit programs, undermined physicians' and patients' freedom to choose appropriate drug therapies and generated additional income through referrals received.

58. Had Government-funded health insurance programs been aware that drugs were prescribed as a result of the conduct alleged in this complaint, they would not have paid the claims submitted as a result of GSK's wrongdoing. For example, in Massachusetts, Medicaid's highest drug expenditures are all for psychiatric drugs, including over \$10.7 for million GSK's Paxil.

59. Because the Government would not have paid GSK's claims, GSK

concealed its illegal activities from the Government as a means of defrauding Government-funded health insurance programs into paying for claims and prescription drugs it otherwise would not have paid.

GSK's Efforts Are Part of the Pharmaceutical Industry's Spending Huge Sums to Persuade Doctors to Prescribe Their Products

60. Spending for prescription drugs has tripled during the last decade, increasing from \$40.3 billion in 1990 to \$189.0 billion in 2004.

61. According to the Kaiser Family Foundation, the pharmaceutical industry spent over \$28 billion on promotional activities in 2004. While such significant costs undoubtedly fuel the rising cost of prescription drugs, the pharmacy industry ignores the effect of such marketing expenses. Amounts spent on kickbacks and marketing activities significantly contribute to the high cost of prescription drugs.

62. While ignoring marketing costs, the pharmaceutical industry, through the Pharmaceutical Research and Manufacturers of America ("PhRMA"), of which GSK is a member, points to the high cost of research and development ("R&D") as one of the primary reasons for the high cost of prescription drugs. PhRMA estimates that the pharmaceutical industry spent 18.7% of sales or \$35.0 billion on pharmaceutical R&D in 2004.

63. PhRMA states:

Just as the cost of a textbook is not determined by the cost of the paper of its pages and the cost of surgery has little to do with the price of the surgeon's scalpel, the cost of a medicine is not simply the cost of its ingredients. Like other products that result from research and creativity, medicines are really made of knowledge — knowledge that prevents and cures disease and relieves suffering.

The knowledge needed to discover and develop new

medicines does not come cheap. Discovering, developing, testing, and gaining regulatory approval for new medicines is expensive, time consuming and risky.

64. Although pharmaceutical manufacturers' marketing and promotion activities exceed their R&D costs, neither PhRMA nor GSK identifies the high cost of marketing as one of the reasons for the high cost of prescription drugs.

65. Pharmaceutical companies now employ over 101,000 sales representatives or more than one for every eleven physicians. Drug company sales representatives, or "detailers," are now at a ratio of 1 to every 9 doctors and doctors interact with 28 detailers per week, while detailers visit medical specialists 14 times per week. Forty-six percent of physicians have reported that drug representatives are "moderately to very important" in influencing their prescribing habits.

66. American Medical Association ("AMA") policy states that "[t]o avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:"

- (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. . . . Cash payments should not be accepted;
- (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads);
- (3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location where, (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering, and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made;

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- (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses;
- (6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policymaking meetings of national, regional or specialty medical associations;
- (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

American Medical Association, Council on Ethical and Judicial Affairs, "Gifts to Physicians from Industry," AMA Ethical Opinion 8.061.

67. AMA policy also sets ethical guidelines for physicians attending continuing medical education ("CME") conferences. AMA policy states that "[t]he

educational value of the CME conference or activity must be the primary consideration in the physician's decision to attend or participate. Though amenities unrelated to the educational purpose of the activity may play a role in the physician's decision to participate, this role should be secondary to the educational content of the conference." American Medical Association, Council on Ethical and Judicial Affairs, "Continuing Medical Education," AMA Ethical Opinion 9.011(2). "Attending promotional activities put on by industry or their designees is not unethical as long as the conference conforms to Opinion 8.061: Gifts to Physicians from Industry and is clearly identified as promotional to all participants." *Id.* at 9.011(4).

68. "[W]hen companies schedule their own conferences at resorts and pay for physicians and their spouses to attend for a weekend that includes only a few hours of lectures and many hours of recreation, lavish meals, and expensive entertainment, it is difficult to view the conference as serving a legitimate educational purpose." Report of the Council on Ethical and Judicial Affairs (Dec. 3, 1990) (explaining AMA Ethical Opinion 8.061).

69. AMA policy also prohibits physicians from accepting "any kind of payment or compensation from a drug company . . . for prescribing its products." AMA Ethical Opinion 6.04 (Fee Splitting); *see also* AMA Ethical Opinion 6.02 (Fee Splitting).

70. The American College of Physicians' Ethics Manual recognizes "drug industry gifts" as having potentially negative influence on clinical judgment and notes that it is "unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells . . . medications that are used in the care of the physician's patients." Ethics Manual, Financial Conflicts of Interest.

71. These ethical guidelines are well intended, attempting to avoid the conflicts of interest that invariably result when kickbacks are paid by drug companies to doctors who have the power to prescribe their products. In fact, studies have found that physicians who accept all-expense paid trips to resorts to attend pharmaceutical symposia alter their prescribing patterns significantly in the period after the symposium, often tripling the number of prescriptions they write for the drug that was the subject of the symposium.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

72. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 71 of this Complaint as if fully set forth herein.

73. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants have knowingly presented or caused to be presented to officers or employees of the United States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid)
(31 U.S.C. § 3729(a)(2))

74. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 73 of this Complaint as if fully set forth herein.

75. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants have knowingly made, used, or caused to be made or

used false records or statements – *i.e.*, the false certifications and representations made or caused to be made by the defendants, to get false or fraudulent claims paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(2).

THIRD CAUSE OF ACTION

(False Claims Act: Making or Using False Record
Or Statement to Avoid an Obligation to Refund)
(31 U.S.C. § 3729(a)(7))

76. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 75 of this Complaint as if fully set forth herein.

77. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants knowingly made, used or caused to be made or used false records or false statements – *i.e.*, the false certifications made or caused to be made by the defendants – to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States.

FOURTH CAUSE OF ACTION

(False Claims Act: Conspiracy)
(31 U.S.C. § 3729(a)(3))

78. Relator repeats and incorporates by reference the allegations contained in Paragraphs 1 through 77 of this Complaint as if fully set forth herein.

79. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the defendants conspired to get false or fraudulent claims paid by the United States and performed one or more acts to effect payment of false or fraudulent claims by the United States.

FIFTH CAUSE OF ACTION

(Violations of Medicare/Medicaid Anti-Kickback Statute)

80. Relator repeats and reincorporates by reference the allegations contained in Paragraphs 1 through 79 of this Complaint as if fully set forth herein.

81. By engaging in the conduct described in the foregoing Paragraphs, defendants have violated 42 U.S.C. §§ 1320a-7 and 42 C.F.R. 1001.952(f).

82. In particular, defendants have knowingly caused physicians and other healthcare providers to submit bills to the United States Government and to Medicaid as a result of the payment of the above-described kickbacks. The payment of kickbacks to induce prescriptions constitutes remuneration to increase the level of business in violation of the anti-kickback statute.

83. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

SIXTH CAUSE OF ACTION

(Violations of the Anti-Kickback Act of 1986)

84. Plaintiff repeats and incorporates by reference the allegations contained in paragraphs 1 through 83 of this Complaint as if fully set forth herein.

85. By engaging in the conduct described in the foregoing Paragraphs, defendants have violated 41 U.S.C. § 53.

86. In particular, defendants have knowingly caused physicians and other healthcare providers to submit bills to the United States Government and to Medicaid as a

result of the payment of the above-described kickbacks. The payment of kickbacks to induce prescriptions constitutes a “thing of value . . . for the purpose of improperly obtaining or rewarding favorable treatment,” which were designed to and in fact did increase the level of business in violation of the anti-kickback statute.

87. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

WHEREFORE, Relator requests that judgment be entered in favor of the United States and Relator against GSK, ordering that:

- a. GSK cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*;
- b. GSK pay an amount equal to three times the amount of damages the United States has sustained because of GSK’s actions, plus a civil penalty of not less than \$5,500, and not more than \$11,000 for each violation of 31 U.S.C. § 3729;
- c. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);
- d. Relator be awarded all costs of this action, including attorneys’ fees and costs pursuant to 31 U.S.C. § 3730(d); and
- e. the United States and Relator recover such other relief as the Court deems just and proper.

By: /s/ Robert A. Magnanini
Robert A. Magnanini (Bar No. 70630)
Signature Code: RAM6635
David S. Stone (admitted pursuant to L. Civ.
R. 83.5.2(b))
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Dated: February 12, 2007